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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,914	05/31/2005	Elise Mona-Lydia Dobin-Assouly	0508-1123	8629

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EXAMINER	
RODRIGUEZ-GARCIA, VALERIE	
ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,914	DOBIN-ASSOULY ET AL.	
	Examiner	Art Unit	
	VALERIE RODRIGUEZ-GARCIA	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-36* is/are pending in the application.

4a) Of the above claim(s) *16,17 and 21-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Receipt of the remarks and amendments filed on August 19, 2008 is acknowledged. Claims 1-13 were cancelled. Claims 14-36 are pending. Claims 16-17 and 21-36 are withdrawn. Claims 14-15 and 18-20 are the subject of this Office Action.

Note

The examiner of this application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Valerie Rodriguez-Garcia, Art Unit 1626.

Priority

This application is a 371 of PCT/FR03/01674, filed on June 4, 2003, which claims foreign priority benefit of application FR 02/06849, filed on June 4, 2002.

Response to Arguments

1. The rejections of claims 14 and 15 under 35 U.S.C. 102(b) as being anticipated by Asher *et al.* are hereby withdrawn because of applicant's amendments.
2. The rejections of claims 18-20 under 35 U.S.C. 103(a) are hereby withdrawn. Applicants traverse the 103 (a) rejection however; the arguments are moot in view of the following new grounds of rejections.

New grounds of rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 14-15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Morimoto *et al.* (Chem. Pharm. Bull. 27 (12); p. 3188-3192 **(1979)**) (cited in the international search report and previous action).

The instant claims are drawn to a composition comprising a water-in-oil-in-water emulsion comprising in it oily phase one or more extractant compounds. There is no limitation in the claims that says that the oil in the oily phase is not the extractant. Therefore, as long as the oil performs the job of "extracting", the limitation of "comprising in its oily phase one or more extractants" has been met.

Morimoto *et al.* teach a multiple water-in-oil-in-water emulsion comprising in its central aqueous phase (w1) NaOH and in its oily phase (o) Arlacel C (nonionic surfactant) and liquid paraffin. The emulsion of Morimoto *et al.* is used for the extraction of drugs from the gastro-intestinal tract (abstract and Chart 1). Applicant's example of de-extractant is NaOH (p. 14 of the specification), which Morimoto *et al.* teach. Therefore, all the claim limitations have been met.

2. Claims 14-15 and 18-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Thien *et al.* (Liquid emulsion membranes and their application in biochemical processing; Separation Science and Technology, 1988, vol. 23 (8-9); p. 819-833)(cited in the international search report).

Thien *et al.* disclose water-in-oil-in-water emulsions comprising in its oily phase a surfactant and a carrier and in its internal aqueous phase a reagent. The prior art discloses biomedical applications of LEMs for drug delivery and drug overdose prevention (p.825). See excerpts from p. 820 and 821.

Liquid emulsion membranes, when applied to biochemical separations, are three-phase systems consisting of a water-in-oil emulsion dispersed into an aqueous third phase (Fig. 1). The system is prepared by slowly adding an aqueous phase to a surfactant-laden oil phase under intense shear. The resulting kinetically stable water-in-oil emulsion is then dispersed using mild agitation into a continuous aqueous phase, resulting in a dispersion of emulsion globules in an aqueous solution. The encapsulated or "interior" phase never actually contacts the "exterior' aqueous phase; the oil acts as a liquid membrane between the two aqueous phases. It is typically assumed that the globules are noncoalescing and thus that they remain their integrity throughout the separation process. In addition, due to the presence of surfactant, the globules are

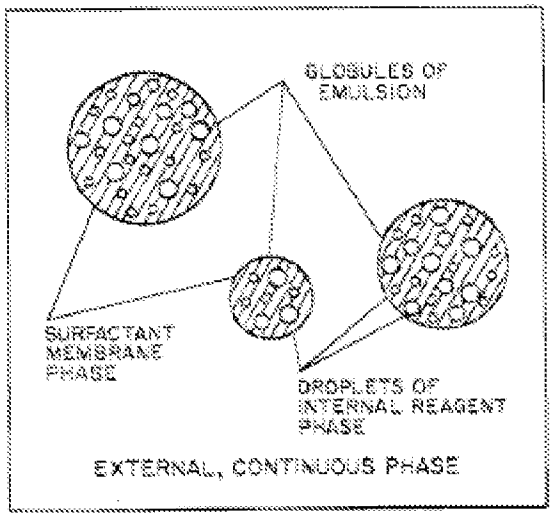

FIG. 1. Schematic of a liquid emulsion membrane system.

In membranes of this type, the interior phase is usually either a concentrated acid or base. In the case of acetic acid, the interior phase is often a concentrated sodium hydroxide (NaOH) solution. Upon

For the carrier in the oily phase see the following excerpts from page 826.

In order to improve their permeability through the membrane, Larson and colleagues added a tertiary amine to the membrane to increase the partitioning of acid into the oil using the following chemistry:

$$R_3N + HAc \rightarrow R_3NH^+Ac^-$$

The addition of this tertiary amine made their system a carrier-facilitated, or Type II, system (Fig. 3). They compared the extraction versus time profiles for Type I and Type II acetic acid LEM systems and found the facilitated system to be much faster (see Fig. 4). In addition, they carried out a series of experiments designed to determine the controlling factors in the LEM-mediated separation of acetic acid. Not surprisingly, they

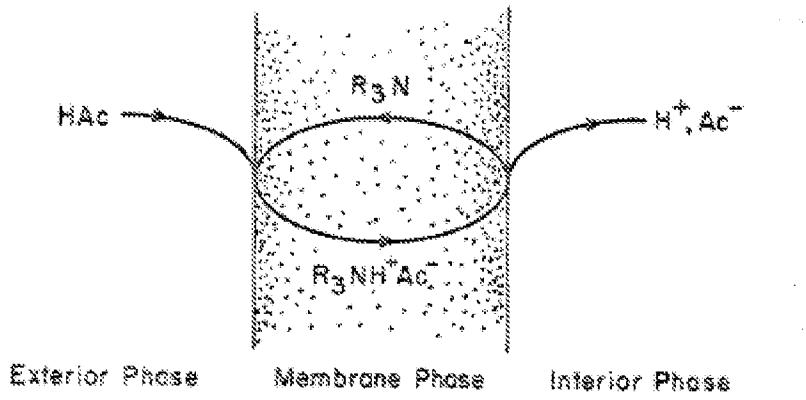

FIG. 3. Schematic of Type II LEM system for acetic acid separation.

Thien *et al.* disclose the carrier (transporter or extractant compound) in the oily phase is a tertiary amine, which applicants also disclose in their examples in the specification, p. 12:

> transporter is a long-chain tertiary amine (R_3N), a molecule with a weak basic character, which is very slightly soluble in water.
>
> At the first interface between the external aqueous phase and the organic phase, the following chemical reaction is produced:
>
> $$HA_{aq} + R_3N_{org} \leftrightarrow R_3NHA_{org}$$

The emulsion of the prior art is brought in contact with a medium comprising acetic acid and acetic acid molecules are extracted from the medium. The same composition with

the same ingredients is taught in the prior art as explained above. Therefore, the instantly claimed composition has been anticipated.

In regards to the recitation "extract from said medium specific toxic molecules capable of binding to said extractant", the claims are drawn to a composition, the intended use of the claimed article does not patentably distinguish the article, since such undisclosed use is inherent in the referenced w/o/w emulsion.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances. Please reference MPEP

§2112. The very teaching of the identical pharmaceutical composition to that presently claimed must necessarily possess the same effects, even though such properties may not have been appreciated in the prior art at the time of the invention.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. MPEP §2112.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14-15 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "with a medium, extract from said medium" of claim 14 makes the claims indefinite. What is the "extract from said medium"? Such recitation is not defined in the claims or the specification. A person of ordinary skill in the art will not be apprised of its meaning.

What exactly is an extractant compound? Every compound can possibly extract something else.

In claim 15, the terms "presented" and "in a single or repeated dose" make the claims indefinite. The pharmaceutical composition was "presented" to whom? In a single or repeated dose in addition to what, a dose of what if there is not active?

Claim 19 recite “lipophilic surfactants”. This is a relative term. Does the lipophilic surfactant includes surfactants with both hydrophilic and lipophilic parts? What HLB values?

Claim 20 recites “de-extractant compounds”. What does de-extractant means? The definition given by applicants to the term in page 2 of the specification is a molecule which will react chemically with the complex formed…An artisan will not be able to envision what compounds qualify as de-extractant. All molecules can chemically react with others given the proper conditions.

Claim Objections

4. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 is a substantial duplicate of claim 14.

Conclusion

Claims 14-15 and 18-20 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/
Primary Examiner, Art Unit 1626

/VALERIE RODRIGUEZ-GARCIA/
Art Unit 1626